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Food Protection Program
Indiana State Dept. Of Health

Request For Variance
State Form 51184 (12/02)
Food Protection Program

INDIANA STATE DEPARTMENT OF HEALTH
Telephone: 317/233-7360 FAX: 317/233-7334

1. Individual Submitting Request: Date: 9/8/08

Name: VICKI S. FARMWALD Telephone: 574 272-5922 Fax: 574 272-6055

Mailing Address: 1501 N. IRONWOOD DRIVE (Number & Street) Email: vfarmwald@haciendafiesta.com

SOUTH BEND (City) IN (State) 46635 (Zip Code) (P.O. Box)

2. Person/Organization Seeking Variance:

Name: HACIENDA MEXICAN RESTAURANTS Email: vfarmwald@haciendafiesta.com

Mailing Address: 1501 N. IRONWOOD DRIVE (Number & Street)

SOUTH BEND (City) IN (State) 46635 (Zip Code) (P.O. Box)

3. Food Establishment(s) for Which Variance is Sought see next page

Include the following information for each food establishment: (List here or attach additional pages if necessary)

- Physical Location (If different than mailing address):
- Mailing Address: 186 Easy Shopping Place Elkhart IN 46516 (Number, Street, City, State, & Zip Code)
- Telephone Number: 574) 294-6597 Fax Number: (574) 522-1367
- Person at each retail food establishment most responsible for supervising: Jennifer Godfrey

4. State how the proposal varies from each rule requirement, citing relevant rule sections by number: (Attach additional pages if necessary)

410 IAC 7-24-195 The rule in question is Reduced Oxygen Packaging. Attached find EXHIBIT A - our standard food handling procedures. We propose to continue these procedures using refrigeration and short shelf, which is acceptable under the FDA 2005 Food Code, Annex 6 - attached EXHIBIT B.

5. Explain how the potential public health hazards and/or nuisances will be alternatively addressed by the proposal. Include supporting studies, Hazard Analysis Critical Control Point (HACCP) Plan(s), standard sanitation operating procedures, and/or any other evidence: (Attach additional pages, if necessary.)

We have used these procedures for over 10 years, having served approximately 40 million meals at multiple locations, with ∅ incidences of botulinum or any other foodborne illness for that matter, traceable to this handling process. In fact, we changed to this system from food cooled in pans and reheated in microwaves for FOOD SAFETY reasons. NOT because it is cheaper or easier for us, but because it is nearly foolproof. It would be a tragedy if we are forced to step backwards to use a system with much more room for error.

3.

618 West Lincoln Avenue Goshen IN 46526

574-534-9590 574-534-7838

John McCarty

6. List how the proposal demonstrates the following (if applicable to the request):

A) How the proposal differs from what is common and usual in similar industry situations:

Our procedures meet federal code and are a commonly accepted and practiced industry standard nationwide.

B) How the proposal is unique and not addressed in existing rules of law:

C) How the proposal does not diminish the protection of public health:

40 million meals served without incident.

D) How the proposal is based on new scientific or technological principle(s):

The supplement to the 2005 FPA food code dated October 5, 2007 states We can use our process because we are preparing and consuming on premises,

E) How the implementation of the variance would be practical:

as seen on attached EXHIBIT C

7. Explain how the person/organization seeking the variance will assure that all provisions of a granted variance will be enacted at each food establishment for which a variance has been granted:

We have in the past and will continue to monitor, record and verify correct procedures of personal hygiene, time and temperature control, avoiding cross contamination and cleanliness and sanitation.

8. List all affected parties known by the person/organization seeking a variance, including all affected regulatory authorities: (Attach additional pages if necessary)

Elkhart County Health Department

Michael Hoover - Food Program Supervisor

Jennifer Bradshaw - Inspector

9. Attach copies of any related variances, waivers or opinions issued by other governmental agencies.

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10. Signature of Individual Making Request: Vicki S. Farmwald

Printed Name, Title: VICKI S. FARMWALD

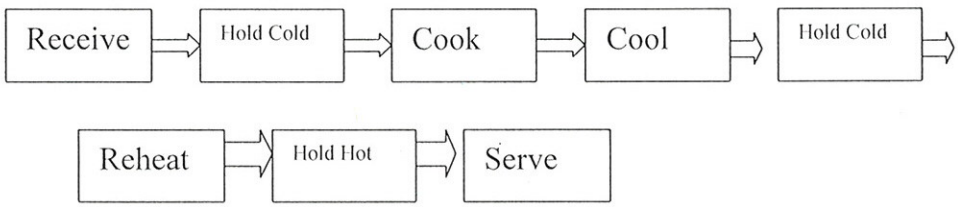
VP of Operations

EXHIBIT A

HACIENDA
MEXICAN RESTAURANTS®

June 2008
Handling procedures for batch preparation
of chicken, taco meat, shredded beef

Flow Diagram



1. Receive the product: raw chicken (frozen), raw ground beef (fresh refrigerated), raw shredded beef (fresh refrigerated)
2. Hold under refrigeration (41°F or lower)
3. Cook in steam jacketed kettle (chicken reach 165°F for at least 15 seconds, ground beef reach 155° for at least 15 seconds, shredded beef reach 145° for at least 15 seconds)
4. Place 1 gallon of product in 2 gallon plastic bags
5. Heat seal bags
6. Date product
7. Properly cool product to 70°F within 2 hours and 41°F within the next 4 hours (using ice baths, freezer or blast chiller).
8. Hold under refrigeration (41°F or lower)
9. Reheat product to 165°F for at least 15 seconds by placing bags into boiling water in rethermalizer
10. Remove product from plastic bags and place in steam table pan
11. Hold in steam table at 135°F or higher
12. Serve
13. All food is used within 4 days of cooking (step 3) or it is discarded

EXHIBIT B

botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. Sanitary safeguards must be employed to prevent reintroduction of pathogens. Chief among these is ***Listeria monocytogenes***.

Clostridium botulinum is the causative agent of botulism, a severe food poisoning characterized by double vision, paralysis, and occasionally death. The organism is an anaerobic spore-forming bacteria that produces a potent neurotoxin. The spores are ubiquitous in nature, relatively heat-resistant, and can survive most minimal heat treatments that destroy vegetative cells. Certain strains of ***C. botulinum*** (type E and non-proteolytic types B and F), which have been primarily associated with fish, are psychrotrophic and can grow and produce toxin at temperatures as low as 3.3°C (38°F). Other strains of ***C. botulinum*** (type A and proteolytic types B and F) can grow and produce toxin at temperatures slightly above 10°C (50°F). If present, ***C. botulinum*** could potentially grow and render toxigenic a food packaged and held in ROP because most other competing organisms are inhibited by ROP. Therefore, the food could be toxic yet appear organoleptically acceptable. This is particularly true of psychrotrophic strains of ***C. botulinum*** that do not produce tell-tale proteolytic enzymes. Because botulism is potentially deadly, foods held in anaerobic conditions merit regulatory concern and vigilance.

The potential for botulism toxin to develop also exists when ROP is used after heat treatments such as pasteurization, or sous vide, processing of foods which will not destroy the spores of ***C. botulinum***. Mild heat treatments in combination with ROP may actually select for ***C. botulinum*** by killing off its competitors. If the applied heat treatment does not produce commercial sterility, the food requires refrigeration to prevent spoilage and ensure product safety. For this reason, sous vide products are frequently flash frozen in liquid nitrogen and held in frozen storage until use.

There is a further microbial concern with ROP at retail. Processed products such as meats and cheeses which have undergone an adequate cooking step to kill ***L. monocytogenes*** can be contaminated when opened, sliced, and repackaged at retail. Thus, a simple packaging or repackaging operation can present an opportunity for recontamination with pathogens if strict sanitary safeguards are not in place.

Processors of products using ROP should be cautious if they plan to rely on refrigeration as the sole barrier that ensures product safety. This approach requires very rigorous temperature controls and monitored refrigeration equipment. If extended shelf life is sought, a temperature of 3.3°C (38°F) or lower must be maintained at all times to prevent outgrowth of ***C. botulinum*** and the subsequent production of toxin. ***Listeria monocytogenes*** can grow at even lower temperatures; consequently, appropriate use-by dates must be established and readily apparent to the consumer. Since refrigeration alone does not guarantee safety from pathogenic microorganisms, additional growth barriers must be provided. Growth barriers are provided by hurdles such as low pH, a_w, or short shelf life, and constant monitoring of the temperature. Any

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EXHIBIT C

3-502.12 Reduced Oxygen Packaging, Criteria.*

1. (D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT *may package* FOOD *using a cook-chill or sous vide process without obtaining a* VARIANCE *if:*
    1. (1) *The* FOOD ESTABLISHMENT *implements a HACCP* PLAN *that contains the information as specified under ¶ 8-201.14(D);*
    2. (2) *The* FOOD *is:*
        1. (a) *Prepared and consumed on the* PREMISES, *or prepared and consumed off the* PREMISES *but within the same business entity with no distribution or sale of the bagged product to another business entity or the* CONSUMER,
        2. (b) *Cooked to heat all parts of the* FOOD *to a temperature and for a time as specified under § 3-401.11,*
        3. (c) *Protected from contamination after cooking as specified under Part 3-4,*
        4. (d) *Placed in a package or bag with an oxygen barrier and sealed before cooking, or placed in a* PACKAGE *or bag and sealed immediately after cooking, and before reaching a temperature below 57°C (135°F),*
        5. (e.) *Cooled to 5°C (41°F) in the sealed* PACKAGE *or bag as specified under §3-501.14, and subsequently:*
            1. (i) *Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held at that temperature until consumed or discarded within 30 days after the date of preparation;*
            2. (ii) *Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the* FOOD *must be consumed or discarded;*
            3. (iii) *Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from packaging, at which time the food must be consumed or discarded; or*
            4. (iv) *Held frozen with no shelf life restriction while frozen until consumed or used.*